

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDICIS PHARMACEUTICAL)
CORPORATION,)
Plaintiff,)
v.) C.A. No. 10-1099 (SLR)
NYCOMED U.S. INC.,)
Defendant.)

**MEDICIS' ANSWERING BRIEF IN OPPOSITION TO
NYCOMED'S MOTION TO DISMISS THE COMPLAINT**

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I. NATURE AND STAGE OF PROCEEDINGS

On February 15, 2011, Nycomed U.S. Inc. (“Nycomed”) filed a Motion To Dismiss The Complaint (the “Motion,” D.I. 10). This is the answering brief of Medicis Pharmaceutical Corporation (“Medicis”) in opposition to that motion.

II. SUMMARY OF ARGUMENT AND STATEMENT OF FACTS

Nycomed’s motion contradicts settled law and clear Congressional intent with respect to patent infringement cases brought under the Drug Price Competition and Patent Term Restoration Act of 1984 (“the Hatch-Waxman Act”). The purpose of the Hatch-Waxman Act is to facilitate the litigation of patent disputes before the launch of a generic product. With its motion, Nycomed is asking the Court to entertain some infringement claims now and some later. In a parallel proceeding currently pending before this Court (Civil Action No. 10-419 (SLR), “the parallel Delaware action”), Medicis filed a complaint for infringement of three patents from the very same family as the patent at issue here. Even if the Court grants Nycomed’s motion, the parallel Delaware action will go forward. There is no logical reason why three patents should be litigated now and a fourth patent later.

Medicis is the holder of New Drug Application (“NDA”) No. 21-758, approved by the United States Food and Drug Administration (“FDA”) for the marketing and sale of the brand name drug Vanos® (fluocinonide) 0.1% cream (“Vanos®”). Vanos® is indicated for the treatment of psoriasis, dermatitis, and corticosteroid responsive dermatoses.

Medicis is also the owner of United States Patent Nos. 6,765,001 (“the ‘001 patent”); 7,220,424 (“the ‘424 patent”); 7,217,422 (“the ‘422 patent”); and 7,794,738 (“the ‘738 patent”) (collectively, “the Vanos® patents”), all entitled “Compositions and Methods For Enhancing Corticosteroid Delivery.” The ‘001, ‘424, and ‘738 patents are listed in the FDA’s *Approved*

Drug Products With Therapeutic Equivalence Evaluations (“the Orange Book”) entry for Vanos®.

Pursuant to 21 U.S.C. § 355(j), Nycomed filed Abbreviated New Drug Application (“ANDA”) No. 20-735 seeking FDA approval to market and sell a generic version of Vanos® before the expiration of the Vanos® patents. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Nycomed included in its ANDA a certification (“Paragraph IV Certification”) alleging that the ‘001 and ‘424 patents will not be infringed by the commercial manufacture, use, or sale of Nycomed’s generic product. Although the statute requires Nycomed to file a certification with respect to the ‘738 patent as well, Nycomed has not done so to date. (See Nycomed Br. (D.I. 12) at 1 (“Nycomed has not made a Paragraph IV certification with respect to the ‘738 patent . . .”))¹

On May 19, 2010, Medicis filed a complaint against Nycomed in the parallel Delaware action for infringement of the ‘001, ‘424, and ‘422 patents. In its complaint, Medicis included a count for infringement of each of the ‘001, ‘424, and ‘422 patents under § 271(e)(2)(A) based on the filing of ANDA No. 20-735 with the FDA. Medicis also included declaratory judgment counts for actual infringement of these three patents under §§ 271(a)-(c).

On August 3, 2010, Nycomed filed motions to dismiss several, but not all, of the infringement claims in the parallel Delaware action. (Civil Action No. 10-419, D.I. 10.) Specifically, Nycomed’s motions sought dismissal of the declaratory judgment counts under §§ 271(a)-(c) and the § 271(e)(2)(A) count with respect to the ‘422 patent for similar reasons as asserted in the present motion. On December 15, 2010, Medicis opposed Nycomed’s motion to

¹ Nycomed also has not filed a patent certification with respect to the ‘422 patent. Unlike the ‘738 patent, however, the ‘422 patent is not listed in the Orange Book. Thus, the statute does not require Nycomed to file a certification with respect to the ‘422 patent. See 21 U.S.C. § 355(j)(2)(A)(vii).

dismiss, explaining in detail how the weight of authority supports the exercise of subject matter jurisdiction for claims of infringement of all relevant patents as long as the ANDA at issue contains at least one Paragraph IV Certification. (Civil Action No. 10-419, D.I. 21.) On January 19, 2011, Nycomed stipulated to dismissal of its motion. (Civil Action No. 10-419, D.I. 24.)

On December 15, 2010, Medicis filed the complaint in this case for infringement of the '738 patent. (Civil Action No. 10-1099, D.I. 1.) Like the complaint in the parallel Delaware action, Medicis included a count for infringement under § 271(e)(2)(A) as well as declaratory judgment counts for actual infringement under §§ 271(a)-(c). On February 15, 2011, Nycomed filed the instant motion to dismiss. (D.I. 11.) Nycomed's arguments are strikingly similar to the arguments made in its previous motion to dismiss, even though Nycomed stipulated to dismissal of that motion.

III. ARGUMENT

Nycomed's motion to dismiss should be denied. First, the Court has subject matter jurisdiction over Medicis' claim for infringement of the '738 patent under 35 U.S.C. § 271(e)(2). Further, the Court may and should exercise declaratory judgment jurisdiction over Medicis' claims of actual infringement of the '738 patent under 35 U.S.C. §§ 271(a), (b), and (c). Finally, judicial economy weighs heavily in favor of litigating all patents now, including the '738 patent.

A. The Court Has Subject Matter Jurisdiction Over Medicis' Claim of Infringement of the '738 Patent Under 35 U.S.C. § 271(e)(2)

Nycomed contends that this Court lacks subject matter jurisdiction to determine infringement of the '738 patent under 35 U.S.C. § 271(e)(2). In particular, Nycomed argues that § 271(e)(2) cannot support a claim for infringement of the '738 patent because Nycomed has not filed a Paragraph IV certification with respect to that patent. The statute is not limited in that fashion. Nycomed's argument is undercut by the express language and clear congressional intent

of § 271(e)(2). Further, several courts facing similar issues have made clear that § 271(e)(2) will support a claim for infringement of a patent even if the ANDA does not contain a Paragraph IV certification specific to the patent-in-suit.

1. Congress Did Not Intend To Limit § 271(e)(2) To Patents Subject To A Paragraph IV Certification

The language, structure, and purpose of the Hatch-Waxman Act make clear that this Court has case or controversy jurisdiction over Medicis' claim for infringement of the '738 patent under § 271(e)(2). Prior to the Hatch-Waxman Act, generic drug manufacturers were required to file an NDA to market a generic version of a brand name drug. Further, the FDA required the generic company to submit its own safety and efficacy data with the NDA. To conduct the tests required to satisfy this requirement, generic companies necessarily had to make and use the drug product in question. This ran afoul of the patentee's right to exclude others from making, using, or selling the invention. *See 35 U.S.C. §§ 271(a)-(c).*²

Thus, prior to the Hatch-Waxman Act, a generic company planning to market a generic version of a patented drug could not conduct tests or develop information until after the expiration of the entire patent term, creating a *de facto* patent term extension for as long as it took to gain regulatory approval. As the Supreme Court pointed out, "the combined effect of the patent law and the premarket regulatory approval requirement was to create an effective extension of the patent term." *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990). Congress implemented the Hatch-Waxman Act to address this issue.

² In *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984), the Federal Circuit confirmed that the manufacture, use, or sale of a patented invention constituted an act of infringement, even if it was for the sole purpose of conducting tests and developing information necessary to obtain regulatory approval.

First, Congress enacted § 271(e)(1), also known as the “Safe Harbor” provision. That section provides that “[i]t shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs.” 35 U.S.C. § 271(e)(1). Thus, the Safe Harbor allows generic drug companies to engage in otherwise infringing activities necessary to obtain regulatory approval prior to the expiration of a patent.

Second, by enacting 21 U.S.C. § 355 *et seq.*, Congress established a new process for the filing and approval of generic drugs that substantially shortened the time and effort it took for a generic company to obtain regulatory approval. Today, a generic company is allowed to “piggyback” on the work of the branded company by submitting an ANDA in place of an NDA. In particular, the generic company is allowed to substitute bioequivalency data in place of full-blown safety and efficacy studies, thus vastly reducing the time and expense needed to gain regulatory approval of a generic drug. *See* 21 U.S.C. § 355(j)(2)(A).

In *Eli Lilly*, the Supreme Court explained, however, that in addition to streamlining the process for regulatory approval of generic drugs, the Hatch-Waxman Act also sought to guard against infringement of patents relating to branded drugs. *See Eli Lilly*, 496 U.S. at 676. The brand company is required to file with the FDA the number and expiration date of any patents that claim the approved drug or the approved use of the drug. The FDA then lists these patents in the Orange Book. Generic companies are required to include in their ANDAs one of four certifications with respect to each patent listed in the Orange Book: (1) that no patent information is listed in the Orange Book (“Paragraph I Certification”), (2) that the patent listed in the Orange Book has expired (“Paragraph II Certification”), (3) that the generic company will

not launch its product until the patent listed in the Orange Book has expired (“Paragraph III Certification”), or (4) that the patent listed in the Orange Book is invalid or will not be infringed (“Paragraph IV Certification”). 21 U.S.C. § 355(j)(2)(A)(vii).

ANDAs containing a Paragraph IV Certification may be approved immediately unless the branded company sues for infringement within 45 days of receiving notice of the Paragraph IV Certification. 21 U.S.C. § 355(j)(5)(B)(iii). Because the Safe Harbor provision was part of the same legislation, however, Congress had to provide a jurisdictional “hook” to allow the patent owner to bring suit. Congress did this by enacting § 271(e)(2)(A). That section states, in relevant part:

It shall be an act of infringement to submit—(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2) (emphasis added).

Thus, it is widely recognized that the Hatch-Waxman Act struck a balance between brand name and generic drug manufacturers. On the one hand, the manufacture and use of a drug product for the purpose of obtaining regulatory approval is not infringement. *See, e.g., Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1132 (Fed. Cir. 1995). “On the other hand, once it is clear that a party seeking approval of an ANDA wants to market a patented drug prior to expiration of a patent, the patent owner can seek to prevent approval of the ANDA” by initiating an infringement lawsuit prior to launch of the generic product. *See id.*

The resolution of Nycomed’s motion to dismiss Medicis’ claim for infringement of the ‘738 patent under § 271(e)(2)(A) comes down to whether the artificial act of infringement

created by that section is limited to patents that are the subject of a Paragraph IV Certification, or whether § 271(e)(2)(A) also provides a jurisdictional basis for resolving disputes involving patents that are not the subject of such certifications. Notably, § 271(e)(2)(A) makes no mention of Paragraph IV Certifications. Rather, the express language of § 271(e)(2)(A) provides a jurisdictional “hook” for any claim of infringement so long as an ANDA has been submitted seeking approval of a generic drug prior to the expiration of any patents covering the brand name drug. This is entirely consistent with the clear congressional intent to set up a process whereby patent disputes could be fully litigated before the launch of a generic drug. *See Teva Pharm. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819 (N.D. Ill. 2004).

In *Teva Pharmaceuticals*, the court addressed an argument very similar to Nycomed’s. In that case, the defendant argued that the jurisdictional basis of § 271(e)(2)(A) is limited to patents listed in the Orange Book and, therefore, the subject of Paragraph IV Certifications. The court rejected this argument, explaining instead that “[t]he language of § 271(e)(2)(A) does not require that the ANDA contain a certification to constitute an act of infringement.” *Id.* at 829. Rather, § 271(e)(2)(A) “only requires that the application be filed under § 355(j).” *Id.* Further, with respect to congressional intent, the court explained that Congress did not intend to limit the artificial act of infringement created by § 271(e)(2)(A) to patents that are the subject of Paragraph IV Certifications:

If Congress had so intended, it could have easily done so. The provision might have read, for example, “It shall be an act of infringement to submit an application containing a certification described in § 355(j)(2)(a)(vii)(IV).” Instead, the provision makes it an act of infringement to submit “an application under Section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355(j)] . . . for a drug claimed in a patent or the use of which is claimed in a patent

Teva Pharm., 301 F. Supp. 2d at 829-30 (emphasis added).

In other words, relying on the express language and clear congressional intent of the statute, the *Teva* court rejected the same argument that Nycomed now makes. Contrary to Nycomed's assertion, the jurisdictional basis of § 271(e)(2)(A) is not limited to patents that are the subject of a Paragraph IV Certification. Indeed, it is not even limited to patents listed in the Orange Book. Rather, the only prerequisite under § 271(e)(2)(A) is the submission of an ANDA under § 355(j) that contains a Paragraph IV Certification. *Id.* As long as that requirement has been met, § 271(e)(2)(A) provides a jurisdictional basis for the assertion of any and all patents covering the branded drug or a use of the branded drug.

2. Several Courts Have Held That § 271(e)(2) Is Not Limited To Patents Subject To Paragraph IV Certifications

In addition to *Teva*, several other courts addressing the scope of § 271(e)(2)(A) have held that the artificial act of infringement is not limited to patents for which a generic company has filed a Paragraph IV Certification. *See, e.g., Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004); *Bayer Healthcare, LLC v. Norbrook Labs, Ltd.*, No. 08-C-0953, 2009 U.S. Dist. LEXIS 126929, at *41 (E.D. Wis. Sept. 24, 2009); *Purdue Pharma Prods. L.P. v. Par Pharm. Inc.*, 642 F. Supp. 2d 329, 363 n.49 (D. Del. 2009).

For example, in *Glaxo*, the patent owner brought a declaratory judgment action against a generic company concerning an ANDA covering a generic version of an antibiotic drug. *Glaxo*, 376 F.3d at 1351. Because antibiotic drugs were not included in the original version of the Hatch-Waxman Act, the patents-in-suit were not listed in the Orange Book, and, hence, the generic company was not required to file Paragraph IV Certifications against those patents. *Id.* at 1345. At trial, the district court found that the generic company willfully infringed the patents-in-suit. On appeal, the Federal Circuit reversed the finding of willful infringement. *Id.* at 1351. In doing so, however, the Court held that "Section 271(e)(2) provides a jurisdictional

basis for a declaratory judgment suit against a generic manufacturer" so long as the manufacturer had submitted an ANDA. *Id.* at 1344. Notably, the Court made no mention of whether the patents-in-suit were subject to Paragraph IV Certifications.

Similarly, in *Bayer Healthcare*, the defendant filed an ANDA with a Paragraph IV Certification but then later withdrew its certification by amendment to its original application. When the plaintiff asserted a claim of infringement under § 271(e)(2), the generic company moved to dismiss, making exactly the same arguments as Nycomed makes here. Rejecting those arguments, the court held that "[i]t would be improper to dismiss the action based on [the generic company's] contention that its application no longer contains a Paragraph IV certification because a Paragraph IV certification is not required to trigger an infringement action under § 271(e)(2)." *Bayer Healthcare*, 2009 U.S. Dist. LEXIS 126929 at *27 (emphasis added). The law could not be clearer. *See also Purdue Pharma*, 642 F. Supp. 2d at 363 n.49 (citing *Bayer* and *Glaxo* and allowing a § 271(e)(2) infringement claim to proceed against a patent against for which no Paragraph IV certification had been filed).

Medicis anticipates that Nycomed will attempt to distinguish *Teva*, *Glaxo Group*, and *Bayer Healthcare* on the ground that these cases involved old antibiotics and animal drug products, which are governed by a different regulatory regime. That argument provides no shelter. Even though the branded drugs at issue in those cases were approved under different sections, the courts' analyses were firmly rooted in the express language of § 271(e)(2)(A). Indeed, the court in *Bayer* rejected the exact same argument that Medics anticipates Nycomed will make. Specifically, the court explained that "[a]lthough the pioneering antibiotic drugs and patents in *Glaxo* and *Teva* were approved under 21 U.S.C. § 357, the courts' analysis and

statutory interpretation were rooted in § 271(e)(2) and; therefore, this inconsistency is irrelevant.” *See Bayer*, 2008 U.S. Dist. LEXIS 126929 at *26-27.

Further, the two cases on which Nycomed relies in support of its position are distinguishable. *See Eisai Co. v. Mutual Pharm. Co.*, No. 06-3613, 2007 WL 4556958, at *1 (D.N.J. Dec. 20, 2007); *Novo Nordisk Inc. v. Mylan Pharms. Inc.*, No. 09-2445, 2010 WL 1372437, at *1 (D.N.J. Mar. 31, 2010). In *Eisai*, the patentee brought patent infringement claims under § 271(e)(2) on a patent that was not listed in the Orange Book. The reason the patent-in-suit was not listed was because the brand name company repeatedly filed the wrong forms and information with the FDA. *Id.* at *4-5. Had the brand company filed the correct forms and information, then the patent-in-suit would have been listed, and this issue would not have been disputed. In dismissing the claim, the court noted that the case was “not a ‘normal’ case.” *Id.* at *14. More importantly, however, the facts of *Eisai* are completely different from the facts here. In *Eisai*, the ANDA in question did not contain even a single Paragraph IV Certification at the time of the complaint. *Id.* at *6. By contrast, in this case, Nycomed filed two Paragraph IV Certifications with ANDA No. 20-735 – one with respect to the ‘001 patent and one with respect to the ‘424 patent.

Likewise, Nycomed’s discussion of *Novo Nordisk* misses the mark. Nycomed admits that this case stands for the proposition that the filing of an ANDA that should, but does not, include a Paragraph IV Certification nevertheless constitutes an “act of infringement” under § 271(e)(2)(A). (Nycomed Br. at 6.) Nycomed then relies on this case, however, to argue that Medicis’ complaint should have, but did not, contain an allegation that “the FDA will require Nycomed to amend its ANDA to include a Paragraph IV certification with respect to the ‘738 patent.” (*Id.* at 7). Nycomed is wrong. Paragraph 15 of Medicis’ complaint specifically states:

Pursuant to 21 U.S.C. § 355(j), Nycomed was required to amend its ANDA No. 20-735 to provide a certification as to the '738 patent. Medicis has not received notice of such a certification to date.

(D.I. 1 at ¶15).

Nycomed cites several other cases out of context, but does not discuss them. (Nycomed Br. at 5.) None of those cases, however, stands for the proposition that a patentee who, like Medicis, properly and timely lists its patents and files suit pursuant to § 271(e)(2) cannot state a claim of infringement against a generic manufacturer whose ANDA contains at least one Paragraph IV Certification.

B. The Court Also Has Subject Matter Jurisdiction Over Medicis' Claims Of Infringement Based On 35 U.S.C. §§ 271(a)-(c)

Nycomed also contends that this court lacks subject matter jurisdiction over Medicis' declaratory judgment counts for future infringement of all three patents-in-suit under §§ 271(a), (b), and (c). (*Id.* at 7.) Here, too, Nycomed is wrong. The Court has and should exercise declaratory judgment jurisdiction over these claims. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

1. The Court Has Declaratory Judgment Jurisdiction

The Supreme Court recently clarified the declaratory judgment standard for patent cases. In *MedImmune*, the Court rejected the Federal Circuit's "reasonable-apprehension-of-suit" test in favor of an "all the circumstances" test. *Id.* at 132 n.11. The Court held that to establish declaratory judgment jurisdiction, a plaintiff need only prove that "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

Id. at 127.

As evidenced by the myriad motions and pleadings currently pending in two separate actions, a substantial controversy exists between the parties concerning the patents-in-suit. Indeed, Nycomed does not (and cannot) dispute this element of the *MedImmune* test. Instead, the heart of Nycomed's argument is directed to second prong of the standard, *i.e.* that the controversy between Medicis and Nycomed is not sufficiently immediate and real to warrant the issuance of a declaratory judgment. (*See* Nycomed Br. at 8.) This argument falls flat. First, in its responsive pleading in a pending New York action, Nycomed admits that a controversy exists with respect to two patents from the same family as the '738 patent. Further, Nycomed's arguments concerning the lack of FDA approval or a final decision to launch its product have been considered and rejected by several courts.

(a) Nycomed Has Admitted That There Is A Substantial Controversy Concerning Related Patents

Nycomed is hard-pressed to argue that the controversy between the parties is not sufficiently immediate and real. Indeed, in its Answer, Affirmative Defenses, and Counterclaims filed in a pending New York action (C.A. No. 10-4140, S.D.N.Y.), Nycomed pled exactly the opposite with respect to the '001 and '424 patents. In support of its own declaratory judgment counterclaims, Nycomed stated that "an actual case and controversy exists between the parties concerning the infringement and validity of the '001 and '424 patents, and that controversy is ripe for adjudication by this Court." (Ex. 1 (C.A. 10-4140-LAK (S.D.N.Y.), D.I. 19) at Counterclaim ¶ 8.) There can be no dispute that this controversy extends to the '738 patent, a continuation of the '424 patent, which itself is a divisional of the '001 patent. Medicis is asserting the '738 patent against the same ANDA for which the '001 and '424 patents were asserted. Nycomed's admission should be dispositive of its motion to dismiss Medicis' claims for future infringement pursuant to §§ 271(a)-(c).

(b) Nycomed's Arguments Concerning FDA Approval And Lack Of A Decision To Launch Have Been Rejected By The Courts

Nycomed also argues that the controversy between the parties is not sufficiently immediate and real because (1) the alleged infringement is contingent on FDA approval and (2) Medicis' complaint "lacks any allegation that Nycomed has made or is planning to make preparations for the launch of its proposed ANDA product." (Nycomed Br. at 8.) Time and again, courts have considered and rejected the very same arguments made by generic companies in the same position as Nycomed. *See Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 693 F. Supp. 2d 409, 419 (D. Del. 2010); *Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338, 351 (D. Del. 2009); *Bayer Healthcare*, 2009 U.S. Dist. LEXIS 126929 at *39-40; *Takeda Pharms. Co. v. Sandoz, Inc.*, No. 07 Civ. 3844 (DLC), 2007 U.S. Dist. LEXIS 74860, at *18-19 (S.D.N.Y. Oct. 9, 2007); *Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1008-09 (N.D. Ill. 2001).

In *Cephalon*, the brand company asserted claims for patent infringement under both § 271(e)(2) and §§ 271(b) and (c). The generic defendant moved to dismiss the §§ 271(b) and (c) claims for lack of subject matter jurisdiction. Denying the motion, the court concluded that a controversy existed under the *MedImmune* standard. Specifically, the court explained:

Defendants have filed the ANDA and have declared their intent to manufacture, market, and sell potentially infringing products in the event that the FDA approves the ANDA. In the context of a § 271(e)(2) infringement action, where the court is engaged in a forward-looking analysis of what defendants will do upon ANDA approval, defendants' declared intent is sufficient to make the controversy real and immediate.

Cephalon, 629 F. Supp. 2d at 351 (citation omitted) (emphasis added).

Likewise, in *Cyclobenzaprine*, the brand company filed patent infringement claims under § 271(e)(2) and sought declaratory relief. Defendants moved for lack of subject matter jurisdiction. Following *Cephalon*, the court once again rejected this argument. Further, the court explained that “[t]o the extent that defendant’s refusal to provide access to the ANDA has concealed the intent of [defendant], the court will not consider dismissal of plaintiffs’ request for declaratory judgment until such access has been granted.” *Cyclobenzaprine*, 693 F. Supp. 2d at 419. Like *Cyclobenzaprine*, Nycomed has refused to provide Medicis with access to its ANDA.³

Similarly, in *Takeda*, the brand company asserted patent infringement claims under § 71(e)(2) and § 271(b). The generic defendant moved to dismiss the § 271(b) claims for lack of subject matter jurisdiction on the same basis that Nycomed asserts here. Specifically, the defendant argued that “it [had] not yet obtained FDA approval” and that “it [had] not made the final business decision to enter the market” for the drug at issue. *Takeda*, 2007 U.S. Dist. LEXIS 74860 at *18-19. The court flatly rejected both of these arguments. Specifically, the court held that the defendant had “taken sufficient action in preparation for an entry into the market to create a dispute that is ‘definite and concrete,’ that touches ‘the legal relations of parties having

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As required by statute, Nycomed’s Notice Letter included an Offer of Confidential Access to ANDA No. 20-735. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), the purpose of the Offer of Confidential Access is to allow the brand name company and patentee to evaluate possible infringement of the patents-in-suit. On May 4, 2010, counsel for Medicis sent counsel for Nycomed proposed revisions to Nycomed’s Offer of Confidential Access. (See Ex. 2). Because the in-house counsel at Medicis who would have primary responsibility for assessing Nycomed’s ANDA are also engaged in patent prosecution and FDA-related matters, Medicis asked Nycomed to remove provisions that would block their access to such materials. On May 11, 2010, counsel for Nycomed sent an email objecting to Medicis’ proposed revisions. (*Id.*). On May 13, 2010, counsel for Medicis sent a letter explaining the rationale for the proposed revisions and asking Nycomed to reconsider its objections. (*Id.*). To date, Nycomed has refused.

adverse legal interests,’ and that is ‘real and substantial.’” *Id.* at *19 (quoting *MedImmune*, 549 U.S. at 127).

In *Teva*, after the brand company did not sue within 45 days of receiving the Notice Letter, the generic defendant asserted declaratory judgment counterclaims for invalidity and noninfringement. The brand company moved to dismiss for lack of subject matter jurisdiction. Denying the motion, the Federal Circuit explained that the act of infringement created under § 271(e)(2) meant that either party would have “an immediate justiciable controversy” against the other as soon as the generic company submitted its ANDA to the FDA. *Teva*, 482 F.3d at 1342.

The cases on which Nycomed relies do not change the analysis. *See Intermedics, Inc. v. Ventrifex Co.*, No. 92-1076, 1993 WL 87405 (Fed. Cir. Feb. 22, 1993); *Teletronics Pacing Sys., Inc. v. Ventrifex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992); *Lang v. Pac. Marine & Supply Co.*, 895 F.2d 761 (Fed. Cir. 1990); *Eisai*, 2007 WL 4556958; *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, C.A. No. 05-590-GMS, 2006 WL 2375035 (D. Del. Aug. 16, 2006); *PSA, LLC v. Gonzales*, 461 F. Supp. 2d 351 (E.D. Pa. 2006); *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925 (N.D. Ill. 1995).

First, except for *Eisai*, all of Nycomed’s cases were decided before *MedImmune*. It is widely recognized that *MedImmune* creates a “more lenient legal standard [that] facilitates or enhances the availability of declaratory judgment jurisdiction in patent cases.” *Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008).⁴

⁴ It is worth noting that even before *MedImmune*’s more lenient standard, courts allowed declaratory judgment actions to proceed in circumstances similar to those present in this case. *See, e.g., Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1571 (Fed. Cir. 1997) (affirming district court’s decision to allow declaratory judgment action to proceed even (continued...)

Moreover, *Abbott* and *Eisai* are distinguishable on a critical point. In both of those cases, the court dismissed the patent owner's § 271(e)(2) counts because the ANDAs at issue did not contain a single Paragraph IV Certification. Because there was no pending action under § 271(e)(2), the courts concluded that the controversy was not "immediate" enough to trigger declaratory judgment jurisdiction. *See Eisai*, 2007 WL 4556958 at *18 ("As discussed previously in this Opinion, Eisai cannot avail itself of § 271(e)(2) here. It therefore cannot establish the immediacy required for a declaratory judgment action without § 271(e)(2)'s 'artificial' act of infringement."); *Abbott*, 934 F. Supp. at 939 ("As explained above, 35 U.S.C. § 271(e)(2) may not be invoked by Plaintiff as a valid cause of action for infringement of its [patent]. Because § 271(e)(2) cannot be invoked, the 'safe haven' provided by § 271(e)(1) remains in force until Defendant begins to market its generic form of [the branded drug]."). As explained above, unlike *Abbott* and *Eisai*, this case involves a valid infringement count under § 271(e)(2). Further, there is no dispute that the ANDA at issue contains multiple Paragraph IV Certifications – one with respect to the '001 patent and another with respect to the '424 patent.

2. The Court Should Exercise Its Declaratory Judgment Jurisdiction

Nycomed argues that "even if this Court were to find that this case presented a live controversy for purposes of declaratory judgment jurisdiction . . . , the Court should in its

though regulatory approval was approximately seventeen months away); *Takeda Chem. Indus., Ltd. v. Watson Pharms., Inc.*, 329 F. Supp. 2d 394, 402-03 (S.D.N.Y. 2004) (holding that case was of sufficient immediacy even though it was possible that the earliest the generic company could market its drug was approximately *seven years* in the future); *Abbott Labs. v. Baxter Healthcare Corp.*, No. 04-C-836, 2004 U.S. Dist. LEXIS 16383, at *18 (N.D. Ill. Aug. 13, 2004) (holding that the "time and cost involved in filing an ANDA indicate an intent to market [the] generic" product); *Glaxo*, 130 F. Supp. 2d at 1008 (noting that the submission of an ANDA is an indication that "defendant is ready or has at least made meaningful preparations to be ready to market the allegedly infringing product").

discretion decline to exercise that jurisdiction.” (Nycomed Br. at 10.) Essentially, Nycomed asks this Court to decline to exercise its discretion at this time, and instead to wait to adjudicate Medicis’ infringement claims under §§ 271(a), (b), and (c) until after Nycomed’s ANDA is approved and it has launched a product on the market. This argument is out of sync with the policies underlying the Hatch-Waxman Act, which allows for early resolution of patent infringement claims upon the submission of an ANDA seeking approval to market a drug covered by a patent.

Nycomed makes three arguments as to why this Court should not exercise declaratory judgment jurisdiction. First, Nycomed asserts that Medicis “prematurely” filed claims of infringement of the ‘738 patent “to generate arguments in opposition to Nycomed’s motion to transfer venue in another action in this district.” (*Id.*) This is baseless speculation that should not inform the Court’s decision regarding whether to accept or reject declaratory judgment jurisdiction in this case. Moreover, Medicis’ claims of infringement cannot be premature for the simple reason, as described above, that these claims are valid under § 271(e)(2) as well as §§ 271(a)-(c). This conclusion is dictated not only by the plain language of the Hatch-Waxman Act, but also by courts that have squarely addressed the issues presented here.

Second, Nycomed asserts that the Court should choose not to exercise declaratory judgment jurisdiction based on Nycomed’s same tenuous arguments as to why declaratory judgment jurisdiction does not exist in the first place, *i.e.*, because “infringement suits [under § 271(e)(2)] must be predicated on an ANDA containing a Paragraph IV certification with respect to the patent-in-suit” and because “the prospect of FDA approval and commercialization are too remote in time to merit judicial intervention now.” (*Id.* at 10-11.) As described above,

Nycomed's arguments are meritless. Thus, Nycomed has not presented a legitimate reason why this Court should not exercise its declaratory judgment jurisdiction.

C. Judicial Economy Weighs In Favor Of Resolving All Patent Infringement Claims at the Same Time

Regardless of the outcome of this motion, the parties will proceed in the parallel Delaware action with respect to the '001, '424, and '422 patents. Although that case is the subject of a motion to transfer to New York, there is no dispute that the parallel Delaware action will go forward in one jurisdiction or another with respect to Medicis' claims of infringement of the '001, '424, and '422 patents under § 271(e)(2)(A) as well as §§ 271(a)-(c). Even if Nycomed were to prevail in all respects on its motion to dismiss, the parallel Delaware action will proceed to discovery and trial of Medicis' claims for infringement of these patents based on the same ANDA at issue here. Thus, discovery and pretrial motions against Nycomed will proceed – either in Delaware or New York – in the same fashion whether Medicis is pursuing its infringement claims under three patents or four. Although Nycomed's motion is irrelevant to the short-term posture of this case, it could have serious consequences over the long term.

Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), the FDA will not grant final approval to Nycomed's ANDA until the earlier of a court decision that the patents-in-suit are invalid or not infringed or October 7, 2012, thirty months from the date on which Medicis received Nycomed's Notice Letter with respect to the '001 and '424 patents. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Presumably, however, the FDA will grant Nycomed tentative approval of its ANDA at some point before either of those dates. As this case approaches the end of the 30-month stay, Medicis will have no choice but to seek leave to amend its pleading to include counts for actual infringement of the '738 patent under §§ 271(a)-(c). At that time, there will be no dispute that Nycomed can threaten to launch its product and, therefore, that declaratory judgment jurisdiction

exists with respect to that patent. There is no reason to make the parties jump through those procedural hurdles when the same counts could be included in the complaint now, and the parallel actions can be consolidated for pretrial proceedings.

There can be no doubt that the statutory scheme of both the Declaratory Judgment and Hatch-Waxman Acts, as well as post-*MedImmune* jurisprudence, favor adjudication of all patent disputes prior to the launch of a generic product. Moreover, as a matter of discretion and efficient use of judicial resources, allowing Medicis' declaratory judgment claims to proceed now, prior to FDA approval and generic entry, provides sufficient time for the parties to resolve their disputes in an orderly manner, and counsels toward adjudicating Medicis' declaratory judgment claims now.

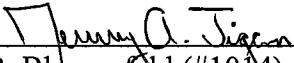
IV. CONCLUSION

For the foregoing reasons, Medicis respectfully requests that the Court deny Nycomed's Motion to Dismiss the Complaint.

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March 18, 2011
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CERTIFICATE OF SERVICE

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I further certify that I caused copies of the foregoing document to be served on March 18, 2011, upon the following in the manner indicated:

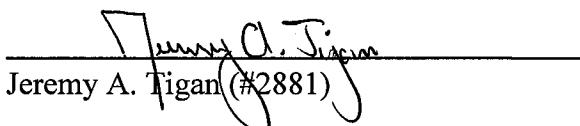
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